

**REMARKS**

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

**I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 15-22 are currently under consideration. Claims 1-4, 7, and 10-12 are newly cancelled, claims 15-21 are re-entered for consideration, and claim 22 is newly added, all without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

Support for new claim 22 can be found throughout the specification as filed, for example, on page 4, line 23 – page 5, line 4, and in Examples 2-4 and 6. No new matter is added.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to clarify the scope of protection to which Applicants are entitled.

**II. THE REJECTION UNDER 35 U.S.C. § 102 IS OVERCOME**

Claim 1 was rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Yamamoto (JP 409143087). The Office Action contends that Yamamoto relates to a topical formulation comprising an extract obtained from *Canavalia gladiata*. The rejection is traversed.

Initially, Applicants respectfully point out that, in order for a Section 102 rejection to stand, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Further, the prior art must contain an enabling disclosure. *See Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). With this in mind, Applicants assert that Yamamoto fails to satisfy the requirements under Section 102, as Yamamoto does not contain all of the elements of the claimed invention.

Applicants draw attention to the instant claims, wherein claim 1 is cancelled, thereby rendering its rejection moot. Moreover, the instant claims are herein directed to a method of

treating acne comprising administering to a subject in need of such treatment a topical formulation which comprises extract obtained from one oriental medicine selected from the group consisting of *Canavalia gladiata* and *Biota orientalis*. To the extent that the rejection applies to the instant claims, Applicants assert that the claims are not anticipated by Yamamoto. Yamamoto does not teach or even suggest a method of treating acne; instead, Yamamoto relates to a preparation for improving skin roughness. Thus, Yamamoto does not contain all elements of the instant claims.

Accordingly, Applicants request for reconsideration and withdrawal of the Section 102 rejection.

### **III. THE REJECTION UNDER 35 U.S.C. § 103 IS OVERCOME**

Claims 1-4, 7, and 10-12 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wakasaya (JP 2001089346) in view of Sugihara *et al.* (JP 355127317) and Basu *et al.* (U.S. Publication No. 20020025348). According to the Office Action, Wakasaya relates to a formulation comprising an extract obtained from the elected species of *Canavalia gladiata*, while Sugihara *et al.* allegedly relates to *Biota orientalis* extracts administered for treating inflammation disorders. Basu *et al.* allegedly relates to *Coptis chinensis* extracts externally administered to treat inflammation disorders. The Office Action alleges that it would have been obvious to one of ordinary skill in the art to modify the teachings of Wakasaya's formulation to include the claimed active ingredients of *Biota orientalis* and *Coptis chinensis* as taught by Sugihara *et al.* and Basu *et al.*, respectively. The rejection is traversed.

Applicants note that claims 1-4, 7, and 10-12 are herein canceled, thereby rendering their rejection moot. To the extent that the rejection applies to the claims currently under consideration, Applicants provide the following remarks.

Establishing a *prima facie* case of obviousness requires that the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP 2143. Further, in order to ground an obviousness rejection, there must be some teaching which would have provided the necessary incentive or motivation for modifying the reference's teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). As stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by

the Office Action does not make the modification obvious unless the prior art suggests the desirability of the modification.” Also, for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants’ disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Furthermore, the Supreme Court has recently reaffirmed the factors set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18: “[T]he scope and content of the prior art are determined; differences between the prior art and the claims at issue are...ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_\_ (2007).

With this under consideration, Applicants asserts that a *prima facie* case of obviousness has not been established, as the combination of Wakasaya, Sugihara *et al.*, and Basu *et al.* does not teach or suggest every limitation of the instant claims. Applicants reiterate that the instant invention is directed to a method of treating acne comprising administering to a subject in need of such treatment a topical formulation which comprises extract obtained from one oriental medicine selected from the group consisting of *Canavalia gladiata* and *Biota orientalis*. The cited references, individually or in combination, do not teach or suggest the claimed method.

In particular, Wakasaya relates to a composition containing extract of seed of sword bean by water and/or organic solvent that may be used for inflammation in the mouth. Wakasaya does not teach or suggest specific oriental medicine such as *Canavalia gladiata*, *Biota orientalis* and *Coptis chinensis*. Furthermore, Wakasaya’s targeted disorder is mouth inflammation, which is very different than acne in both the cause of disorder and the curing method or mechanism. Therefore, Wakasaya does not teach or suggest the claimed invention.

Sugihara *et al.* relates to a composition comprised of extracts from one or two or more crude drugs selected from *Drynaria fortunei*, leaves of *Biota orientalis*, *Sanguisorba officinalis Linn. Var. carnea Regel*, lotus roots, leaves of *Artemisia princeps PAM.*, leaves of *Juniperus communis L.*, leaves of Sugis, roots of *Panax notoginseng Burkill*, Lycium bark, and roots of *Rubia akane Nakai*. The composition allegedly contains antiplasmin (antifibrinolytic) and anti-inflammatory action, but there is no teaching or suggestion that the composition can be used to

treat acne. Therefore, Sugihara *et al.* does not teach or suggest all limitations of the claimed invention.

Basu *et al.* teach that a composition comprising one or more of the following herbs: Hou Po (*Magnoliae officinalis*), Huang Bai, which is also often referred to as Huang Bo (*Phellodendron chinense*), Huang Lian (*Coptis chinensis*), Huo Xiang (*Agastaches rugosa*), Pao Jiang (*Zingiberis officinalis*), Qin Pi (*Fraxinus rynchophylla*), and Zhi Gan Cao (*Glycyrrhizae inflata*). The composition may be used to treat inflammatory bowel disease, irritable bowel syndrome, and inflammatory and other related conditions such as arthritis. Basu *et al.* does not teach or suggest using the composition for the treatment of acne as claimed.

Therefore, individually, the cited references do not teach or suggest a method of treating acne as claimed. Furthermore, the cited references in combination do not teach or suggest a method of treating acne, as none of the references provide such a teaching or suggestion.

Applicants further reiterate that Sugihara *et al.* relates to a composition comprised of extracts from one or two or more crude drugs selected from *Drynaria fortunei*, leaves of *Biota orientalis*, *Sanguisorba officinalis Linn. Var. carnea Regel*, lotus roots, leaves of *Artemisia princeps PAM.*, leaves of *Juniperus communis L.*, leaves of Sugis, roots of *Panax notoginseng Burkll*, Lycium bark, and roots of *Rubia akane Nakai*. Therefore, in order for Sugihara *et al.* to be applied as described in the Office Action, one skilled in the art would have to choose *Biota orientalis* from among the 10 extracts recited in Sugihara *et al.* with the desired expectation. Clearly, there is no guidance in Sugihara *et al.* that would lead the skilled artisan to choose *Biota orientalis* to arrive at the invention of claims 1, 2, 7, and 10, or would lead the skilled artisan to choose *Biota orientalis* to combine with the formulation of Wakasaya in order to arrive at the instant.

Similarly Basu *et al.* relates to a composition comprising one or more of the following herbs: Hou Po (*Magnoliae officinalis*), Huang Bai, which is also often referred to as Huang Bo (*Phellodendron chinense*), Huang Lian (*Coptis chinensis*), Huo Xiang (*Agastaches rugosa*), Pao Jiang (*Zingiberis officinalis*), Qin Pi (*Fraxinus rynchophylla*), and Zhi Gan Cao (*Glycyrrhizae inflata*). In order to arrive at the invention of instant claims, one skilled in the art would have been expected to choose Huang Bai (*Coptis chinensis*) from among the 7 herbs recited in Basu *et al.* with the desired expectation. There is no guidance in Basu *et al.* that would lead the skilled

artisan to choose *Coptis chinensis* to combine with the formulation of Wakasaya and with *Biota orientalis* of Sugihara *et al.* in order to arrive at the claimed invention.

Hence, the combination of the cited references does not render the claimed invention as unpatentable, as there is no teaching or suggestion of every limitation of the instant claims. Accordingly, reconsideration and withdrawal of the rejection under Section 103 are requested.

**CONCLUSION**

This application is in condition for allowance. Favourable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favourably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,

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